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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,736	07/21/2003	Masahiro Okuda	Q76592	2795

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,736	OKUDA, MASAHIRO	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-21 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-21 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The remarks and amendment filed 3/26/08 are acknowledged.

Claims 6-21 and 24-27 remain under examination.

Withdrawal of Rejections

The objections and rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 3/26/08.

Terminal Disclaimer

The terminal disclaimer filed on 12/20/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 11/050,766 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

Claims 6-8, 10-14, and 19-21 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brown (US 5,314,695) in light of Webster's Dictionary .

Claims 6 and 8-13 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Smirnov et al. (1999; "Smirnov") in light of Webster's Dictionary. These rejections are reinstated due to the cancellation of the New Matter.

Applicant argues that neither of Brown nor Smirnov et al. disclose a reagent kit prepared by combining two reagents, each of which has a specific PS concentration, as recited in the present claims wherein the two reagents used in the claimed kit have different contents of PS to the total content of the phospholipids. Applicant asserts that neither Brown nor Smirnov et al. teach or suggest that lupus anticoagulant (LA) can be

detected by measuring coagulation times using a specific combination of two reagents, each having specific PS concentration and having different PS content ratios.

In response to the argument that Brown and Smirnov are silent as to measuring coagulation time of blood containing LA and that the references do not teach or suggest that LA can be measured by measuring coagulation times as a combination of two reagents having different PS content ratios, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The claims are drawn to a reagent kit comprising phospholipids in various amounts and ratios. Both Brown and Smirnov teach the claimed reagents. Hence, the prior art reagents are capable of the intended use.

In response to the argument that neither Brown nor Smirnov et al. disclose a reagent kit prepared by combining two reagents, each of which has a specific PS concentration, wherein the two reagents used in the claimed kit have different contents of PS to the total content of the phospholipid, Applicant is directed to the liposomes taught by Brown, comprising liposomes having different ratios of PS, PE, PG and PC. In Table I, col. 10, the ratio of phospholipids is 1:1:1:0 (PC:PE:PS:PG). The ratio of PL for entries 10 and 11 are 10:0:1:0 and 20:1:1:0, respectively. Entries 10 and 11 represent a 10 and 20-fold dilution of PS compared to the ratio of PL in the first entry.

Regarding Smirnov, the reference discloses liposomes PC, PE and varying percentages of PS. The legend of Figure I discloses that the concentration of PS was 1, 3, 5, 7, 10, 15 and 20% of the total PL (PS, PE and PC which corresponds to the darkened symbols). Figure 1A and 1B disclose liposomes having varying rations of PS wherein the PS concentration varies.

Claims 6 and 8-12 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moore et al. (EP 566,333) in light of Webster's Dictionary.

Applicant argues that Moore discloses reagents for APTT and PT containing synthetic phospholipids. Applicant argues that Moore does not teach kit preparation by combining two reagents, each of which has a specific PS concentration, with the PS concentrations in being different from each other; a PS content ratio in the first reagent that is different from a PS content ratio in the third reagent (where PS content ratio = (PS content) / (PL content)); and LA detection based on a first coagulation time obtained by using the first and second reagents, and a second coagulation time obtained by using the third and fourth reagents. Applicant argues that the reagent kit of the present invention is the combination of two reagents having the above features (a) and (b), and details disclosure by the instant specification regarding its method of use. Applicant asserts that the instantly claimed kit allows for the discrimination of LA-positive samples in its method of use.

Responding to Applicant's arguments that Moore doe not teach kit preparation to provide differing ratios of PS and the method of using the kit for LA detection, the

instant claims are directed to a kit that is comprised of certain reagents, some of which have a

certain concentration range. The kit is not a method. The limitations of the claims are met as long as the reference discloses the claimed elements of the kit. Moore teaches multiple combinations of reagents that meet the claimed elements of the kit.

In response to applicant's arguments, the recitation "for detecting lupus anticoagulant in blood" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claims 13, 21, 24 and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Moore et al. (EP 566,333) and Webster's Dictionary in view of Smirnov et al. (1999).

Applicant argues that Moore and Smirnov fail to teach the combination (claim 13 composition) that can discriminate an LA-positive sample from an abnormal one. Applicant concludes that the combined teachings of Moore and Smirnov do not make claim 13 obvious.

Applicant's argument is not directed to the factual basis of the rejection and is, therefore, non-persuasive.

Claims 14-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. (EP 566,333) and Webster's Dictionary in view of Rosen et al. (US 6,395,501).

Claims 7, 13, 21, and 24-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. (EP 566,333; cited in the IDS filed 10/4/05) and Webster's Dictionary in view of Smirnov et al. (1999; previously cited), as applied to claims 13, 21, and 24, in further view of Rosen et al. (US 6,395,501).

Applicant Argues that Rosen does no remedy the alleged deficiencies in the cited references. Applicant asserts that Rosen does not disclose the features of the invention (a) to (c) as enumerated on page 11 of the instant response.

Applicant's argument is not directed to the factual basis of the rejection and is, therefore, non-persuasive. Rosen was cited to teach coagulant activators and their usefulness in the reagent kits taught by the references indicated for these rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651